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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

ILLUMINA, INC., and
ILLUMINA CAMBRIDGE LTD.,

Plaintiffs,

v.

BGI GENOMICS CO., LTD.,
BGI AMERICAS CORP.,
MGI TECH CO., LTD.,
MGI AMERICAS, INC., and
COMPLETE GENOMICS INC.,

Defendants.

COMPLETE GENOMICS INC.,

Counterclaim-Plaintiff,

v.

ILLUMINA, INC., and
ILLUMINA CAMBRIDGE LTD.,

Counterclaim-Defendants

Case No. 3:19-cv-03770-WHO

**DECLARATION OF MARK VAN OENE
IN SUPPORT OF PLAINTIFFS
ILLUMINA, INC. AND ILLUMINA
CAMBRIDGE LTD.'S MOTION FOR
PRELIMINARY INJUNCTION**

Date: March 25, 2020

Time: 2:00 p.m.

Courtroom: 2, 17th Floor

Hon. William H. Orrick

1 1. I, Mark Van Oene, have personal knowledge of the following facts, or believe them
2 to be true based upon information provided to me by others and a reasonable investigation. I would
3 testify that the below facts are true and correct to the best of my knowledge if called upon to do so.

4 2. This declaration includes facts known to me at the time of declaration. I reserve the
5 right to supplement or amend in the future, including through testimony given at deposition or trial.

6 **I. BACKGROUND**

7
8 3. I am the Chief Commercial Officer at Illumina, Inc. and have held this position since
9 November 2016. Previously, I was promoted to Senior Vice President of Americas Commercial
10 Operations at Illumina, Inc. in April 2016 after serving as the Vice President of Americas
11 Commercial Operations since January 2014. Before that, I was Vice President of Worldwide Sales.
12 I served Illumina, Inc. in that capacity, starting in January 2012.

13 4. I am aware that Illumina Cambridge LTD. (“Illumina Cambridge”) owns the rights
14 to U.S. Pat. No. 7,566,537 (“the ’537 patent”) and U.S. Patent No. 9,410,200 (“the ’200 patent”).
15 I am also aware that Illumina, Inc. is the exclusive licensee to the ’537 and ’200 patents in the U.S.
16 Both Illumina Cambridge and Illumina, Inc. have a role in selling sequencing products in the United
17 States. Specifically, the companies operate under a toll manufacturing model whereby Illumina
18 Cambridge owns product inventory in the United States and sells products to Illumina Inc. through
19 a flash title transfer. Illumina, Inc. then resells the sequencing products to our United States
20 customers and is the exclusive distributor for Illumina Cambridge. Both parties share profits earned
21 from the sale of sequencing instruments. Unless I note otherwise, I refer to both parties collectively
22 as “Illumina.”

23 5. In the course of my duties, I am familiar with the marketing and sales of Illumina
24 products, including its DNA sequencing instruments. I am familiar specifically with trends in
25 demand for next-generation sequencing, or “NGS” instruments. I am knowledgeable about industry
26 trends in general but also specifically about Illumina’s competitors, Illumina’s target customers,
27 and customer purchasing habits unique to this industry.

28 6. I obtained a Bachelor of Science degree at The University of Western Ontario in

1 1995.

2 7. I started working at Illumina in January 2006 and led sales in both Canada and the
3 United States before moving into the role as Vice President of Worldwide Sales. Before Illumina,
4 I was the Director of Genotyping Services at Ellipsis Biotherapeutics, where I led both the
5 laboratory and commercial operations for their services business.

6 **II. SEQUENCING BY SYNTHESIS TECHNOLOGY**

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8 8. Illumina revolutionized the genetics field by commercializing a very successful
9 method of DNA sequencing known as “sequencing by synthesis.” This is often referred to generally
10 as “SBS” technology. Illumina Cambridge (which was previously named Solexa Limited)
11 developed the sequencing-by-synthesis technology that became the basis of Illumina’s market
12 leading next-generation sequencing (NGS) systems, which is also known as Solexa sequencing.

13 9. I understand that the ’537 and the ’200 patents are the Illumina patents at issue in
14 this case, and they are each directed to a “method of labeling a nucleic acid molecule.” I have been
15 informed that these patents cover important aspects of the chemistry (which is based on the use of
16 modified nucleotides with a 3’-azidomethyl blocking group) that are one of the key foundations to
17 Illumina’s Solexa sequencing.

18 **III. ILLUMINA’S SEQUENCING PRODUCTS**

19 10. Over the last decade, Illumina has established its Solexa sequencing as the premier
20 DNA sequencing method in terms of efficiency, accuracy, and reliability. In 2014, Illumina showed
21 how its technology could be used to achieve the biotechnological milestone of sequencing the
22 genetic code of a single human being for only \$1,000. Since then, Illumina’s technology has driven
23 the cost of sequencing a whole human genome to below \$800. Ex. A (2020 JP Morgan Healthcare
24 Conference Presentation) at 8.

25 11. In 2014, Forbes Magazine published an article that described the major impact of
26 Illumina’s achievement:

27 It’s a milestone of huge psychological importance for the scientists who study
28 human genetics and the industry of biotechnology companies creating new
diagnostic tests and drugs using the technology. Initially, the number was put out

there by researchers as kind of a thought experiment, or a mythic totem. Less than a decade ago, the cost of decoding a human genome was \$250,000, but thanks in part to Illumina, the efficiency of the machines has risen at an exponential rate, outpacing the famous Moore's Law that describes the improvement of the semiconductor chips used in supercomputers.

Ex. B ("The \$1,000 Genome Arrives – For Real, This Time," Forbes (Jan. 14, 2014)) at 2.

12. Today, because of its proprietary technology, Illumina is the leading supplier of NGS instruments. Industry experts recognize Illumina as the leading brand for NGS instruments. Ex. C ("Comparison of the MGISEQ-2000 and Illumina HiSeq 4000 sequencing platforms for RNA sequencing", Genomics & Informatics (Sept. 27, 2019) at 1, *available at* <https://bit.ly/3bTBzOM>). ("Illumina sequencers are the globally leading sequencing platform in the next-generation sequencing market."); Ex. D (Next Generation Sequencing (NGS) Market Size, Growth and Trends (2016-2022), DeciBio (Sept.26, 2019)) at 67 [REDACTED]

[REDACTED]. Illumina sells a number of models of next-generation sequencing platforms that all use the Solexa sequencing developed by Illumina Cambridge. These sequencing platforms generate three main revenue streams for Illumina: (i) sales of the sequencing platforms themselves; (ii) sales of sequencing kits and reagents (known as "consumables") for use with those platforms; and (iii) sequencing and product support services. Illumina's reagents are proprietary and are designed for use with its sequencers. There are technical and contractual reasons why Illumina's reagents cannot be used with non-Illumina sequencing platforms and why non-Illumina reagents cannot be used with Illumina's sequencers.

13. Illumina's sequencing platforms include, for example, the Illumina iSeq 100 ("iSeq"), the NovaSeq 6000 ("NovaSeq"), the MiniSeq System ("MiniSeq"), the Illumina NextSeq Series ("NextSeq"), the Illumina MiSeq System ("MiSeq"), and the Illumina MiSeqDX System ("MiSeqDx"). The iSeq was launched in January 2018, the NovaSeq in January 2017, the MiniSeq in January 2016, the NextSeq in January 2014, and the MiSeq in 2011. The MiSeqDX, which has all the capabilities of the MiSeq but is more specifically targeted for use in clinical laboratories, was launched two years after the MiSeq, in 2013. In January 2020, Illumina announced the NextSeq 1000 and NextSeq 2000, which will begin shipping later this year. The iSeq, MiniSeq, and MiSeq systems are capable of producing between 1.2 and 15 Gb per run (1GB is 1 billion bases), the

1 NextSeq systems are capable of producing 120 Gb per run, and the Novaseq system (as well as
2 Illumina's earlier production-scale HiSeq series) are capable of producing 1,500 to 6,000 GB per
3 run. These sequencers all use Illumina's proprietary Solexa sequencing.

4 14. The MiniSeq provides more affordable, streamlined workflow than other sequencing
5 technology. The MiniSeq is a more compact, accessible desktop device well-suited for clinical
6 settings. Historically, Illumina sequencing products, such as the HiSeq series, were typically larger
7 and marketed to large-scale research facilities or larger laboratories. With the MiniSeq, Illumina
8 has integrated for the first time in a single sequencing instrument the tools for every step of the
9 sequencing process from library preparation through sequencing and data analysis. In this way, the
10 MiniSeq offers customers an easy-to-use, "load and go" solution for their sequencing needs. The
11 MiniSeq is well-suited for examining single genes or entire pathways. An image of the MiniSeq
12 appears below:



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20 Available at <https://www.illumina.com/systems/sequencing-platforms/miniseq.html>.

21 15. The NextSeq 500 is slightly more expensive than the MiniSeq and designed for
22 higher volume sequencing. The NextSeq 500 also integrates in a single instrument the tools for
23 many steps of the sequencing process, including for example bioinformatics, the final step of
24 analyzing the sequencing patterns. The NextSeq 500 simplifies the sequencing process and makes
25 SBS technology approachable for "everyday genomics." Ex. E (Sequencing Systems brochure) at
26 8. An image of the NextSeq 500 appears below:



Ex. E (Illumina Sequencing Systems brochure) at 5.

16. The MiSeq is well-suited for targeted and small-genome sequencing. By integrating various steps of the sequencing process into one instrument, the MiSeq also offers customers an “end to end” solution for their sequencing needs. An image of the MiSeq appears below:



Ex. E (Illumina Sequencing Systems brochure) at 4.

17. The MiSeqDX has all the capabilities of the MiSeq but is specifically designed for clinical laboratories that perform screening and diagnostic testing. It is the first FDA-cleared, in vitro diagnostic NGS system on the market. It offers a small footprint, an easy to follow workflow, and data output tailored to the needs of clinical laboratories. An image of the MiSeqDX appears below:



Ex. E (Illumina Sequencing Systems brochure) at 4.

18. The NovaSeq 6000 is a production-scale sequencer launched in January 2017 that also uses Illumina's Solexa sequencing. The NovaSeq 6000 is Illumina's highest-throughput sequencer and enables users to more easily conduct large-scale genomics projects with greater sample volumes, and with more breadth and depth in the genome. Before the release of NovaSeq, Illumina launched the HiSeq Series ("HiSeq"), which includes a number of high-throughput sequencers, including the HiSeq X Ten, which was announced in 2014. An image of the NovaSeq 6000 appears below:



Ex. F (NovaSeq 6000 brochure) at 2.

19. Illumina's NGS products are the primary driver of Illumina's annual revenues. Sequencing instruments and consumables used with the instruments (including, for example, reagents and flow cells) represented approximately 82% of Illumina's 2018 annual revenues. Ex. G (Illumina 10-K (Feb. 11, 2019)) at 6. Illumina, Inc. acquired Solexa, Inc. in 2006 for

1 approximately \$600 million, and Illumina has invested well over \$1 billion in research and
 2 development of SBS technology since 2011. Ex. KK (“Illumina, Inc. Signs Definitive Agreement
 3 To Acquire Solexa, Inc. For \$600 Million In Stock”, BioSpace, (Nov. 13, 2006), *available at*
 4 <https://bit.ly/2PaYmMy>). Illumina’s research and development expenses for the fiscal years ending
 5 on December 29, 2019, December 30, 2018, December 31, 2017, and January 1, 2017 were \$647
 6 million, \$623 million, \$546 million, and \$504 million, respectively. Ex. G (Illumina 10-K (Feb.
 7 11, 2019)) at 8; Ex. H (“Illumina Reports Financial Results for Fourth Quarter and Fiscal Year
 8 2019,” Illumina Press Release (Jan. 29, 2020)). [REDACTED]

9 [REDACTED]
 10 [REDACTED]
 11 [REDACTED]

12 20. Illumina’s Solexa sequencing provides unique advantages in combining high
 13 throughput and high accuracy in a cost-effective manner. This has been important to Illumina’s
 14 commercial success and is an important driver of customer demand because it is recognized for its
 15 ease of use, efficiency, cost, speed, and accuracy. Researchers in the industry have stated that
 16 “Illumina sequencers are the globally leading sequencing platform in the next-generation
 17 sequencing market.” Ex. C (“Comparison of the MGISEQ-2000 and Illumina HiSeq 4000
 18 sequencing platforms for RNA sequencing,” Genomics & Informatics (Sept. 27, 2019) at 1,
 19 *available at* <https://bit.ly/3bTBzOM>).

20 **IV. MGI’S SEQUENCING PRODUCTS**

21 21. MGI Americas, Inc. and MGI Tech Co., Ltd. (which I refer to collectively as “MGI”
 22 in this declaration) are affiliates of the BGI Group, a Chinese company headquartered in Shenzhen,
 23 Guangdong, China. MGI offers several next-generation sequencing platforms, including: (i) the
 24 DNBSEQ-G50 (previously the MGISEQ-200); (ii) the DNBSEQ-G400 (previously the MGISEQ-
 25 2000); and (iii) the DNBSEQ-T7. The DNBSEQ-G50 is a benchtop system, which is advertised as
 26 producing between 10.5-60 Gb per run. The DNBSEQ-G400 is a production-scale sequencer,
 27 which is advertised as producing between 75-1,440 Gb per run. The DNBSEQ-T7 is a production-
 28

1 scale sequencer, which is advertised as producing between 1,000-6,000 Gb per run.

2 22. Very recently, MGI notified Illumina that it plans to distribute the DNBSEQ-G400
3 sequencer to “five or fewer KOLs [key opinion leaders] on a no-cost basis” in the U.S. Ex. FF
4 (MGI email chain of January 24-February 13, 2020) at 7. MGI launched the DNBSEQ-G400 (then
5 called the MGISEQ-2000) back in October 2017 and has been marketing it since that time. Ex. GG
6 (“MGI Tech MGISEQ-2000, MGISEQ-200 Sequencers; MGIFLP Modular NGS Workstation;
7 MGIUS-R3 Robotic Ultrasound System,” GenomeWeb (Oct. 31, 2017), *available at*
8 <https://bit.ly/2SXSzJ>).

9 23. I understand that Illumina has strong evidence that it has relied on in other patent
10 infringement suits in Europe that MGI uses Illumina’s Solexa sequencing. MGI markets its
11 instruments as lower-cost substitutes for Illumina sequencers using the same NGS technology.
12 MGI is able to offer artificially lower prices in part because it did not have to make the substantial
13 research and development expenditures that Illumina incurred in order to acquire and develop
14 Solexa sequencing and related innovations that are the subject of the ’537 and ’200 Patents.

15 **V. OVERVIEW OF THE PURCHASING ENVIRONMENT FOR SEQUENCING** 16 **INSTRUMENTS**

17 24. The following is an overview of the current purchasing environment for sequencing
18 instruments.

19 **A. The Use Of NGS Instruments Continues to Rapidly Expand.**

20 25. The NGS market is still at a relatively early stage. The understanding of the human
21 genome is in its infancy, and sequencing has the potential to increasingly become a part of everyday
22 life as genetics becomes more important to personalized medicine. In personalized medicine,
23 genetic testing can be employed to selecting appropriate and optimal therapies tailored to the
24 individual patient based on the context of a patient’s genetic sequence. Continued growth in the
25 market for NGS instruments is expected due to increasing applications for NGS, including genetic
26 screening, diagnosis, and therapy, as well as the increase in speed, cost, and accuracy of sequencing
27 enabled by Illumina’s technology. As of 2019, less than 0.01% of genomic species and less than
28 0.02% of human genomes have been sequenced, and less than 1% of variants in the human genome

1 have been fully characterized, which shows that there is tremendous growth potential for NGS in
 2 the future. Ex. I (2019 JP Morgan Healthcare Conference Presentation) at 6, 14, 24-25. As just
 3 one example, NGS is expected to become increasingly important for cancer care, as current
 4 adoption levels for early screening, therapy selection, and cancer monitoring are at a very early
 5 stage. Ex. A (2020 JP Morgan Healthcare Conference Presentation) at 8. Illumina's revenues,
 6 which are driven by NGS-related sales and services, have seen consistent and substantial growth
 7 every year since at least 2014, and Illumina's revenues have been projected to grow by about 9-
 8 11% in FY2020. *Id.* at 3-4. Industry analysts have reported that the "global next-generation
 9 sequencing market was USD 4.18 billion in 2018 and is estimated to reach USD 11.06 billion" by
 10 2025. Ex. J ("Global Next Generation Sequencing Market 2029 by Company, Regions, type and
 11 Application, Forecast to 2025 from eSherpa Market Reports," Expedition 99 (Jan. 30, 2020) at 1,
 12 *available at* <https://bit.ly/2uia7e>). Additionally, industry analysts report that "[t]he North America
 13 DNA sequencing products market reached a value of US\$ 1.43 Billion in 2018" and forecast it to
 14 reach \$3.34 billion by 2024. Ex. K ("North America DNA Sequencing Products Market: Industry
 15 Trends, Share, Size, Growth, Opportunity and Forecast 2019-2024," ResearchandMarkets.com
 16 (Jan. 14, 2020) at 1, *available at* <https://yhoo.it/2P5Yo88>). The expected growth of the market in
 17 North America was attributed to factors such as (a) "[t]he presence of high R&D investments
 18 pertaining to new drug discoveries and developments," (b) "high healthcare expenditures in the
 19 region," (c) the "growing geriatric population and prevalence of several chronic diseases," and (d)
 20 "the presence of prominent drug manufacturers and availability of skilled professionals in the
 21 healthcare sector." *Id.* at 2.

22 **B. Suppliers Routinely Engage With Key Opinion Leaders As Part Of A**
 23 **Commercial Rollout**

24 26. In the genetic sequencing field, targeted engagement with a limited number of key
 25 opinion leaders ("KOLs") is a typical part of a commercial launch strategy. Illumina often engages
 26 with a select number of key opinion leaders as a normal part of a commercial rollout and its product
 27 marketing efforts. Other companies in the sequencing industry also frequently supply instruments
 28 or reagents to key opinion leaders for trials or testing as a part of their commercial launch strategies.

1 Examples of such companies include Oxford Nanopore Technologies, Thermo Fisher Scientific,
2 and Pacific Biosciences of California, Inc.

3 27. The placement of sequencers with key opinion leaders is important for a supplier's
4 commercial reputation because key opinion leaders can have substantial influence on the industry's
5 perception of a brand and the purchasing decisions of other customers in the field. The use of a
6 company's sequencers by a key opinion leader in this field (e.g., a prestigious university or research
7 center) is viewed by other institutions as a stamp of approval or endorsement of the supplier's
8 technology, which encourages others in the field to adopt it. For example, Illumina's placement of
9 its sequencing systems at prestigious institutions such as the Broad Institute of MIT and Harvard
10 (among many other highly prestigious Illumina partners) has been important for enhancing
11 Illumina's commercial reputation and driving sales. Acceptance and promotion of a company's
12 technology by key opinion leaders provides a significant opportunity to build the global reputation
13 of a particular technology and that company's brand. The U.S. contains many key opinion leaders,
14 including scientists associated with world renowned institutions with global reputations in
15 sequencing expertise such as the Broad Institute of MIT and Harvard, Cold Spring Harbor
16 Laboratory, HudsonAlpha Institute for Biotechnology, Stanford Genome Technology Center, Mayo
17 Clinic, Baylor College of Medicine Human Genome Sequencing Center, McDonnell Genome
18 Institute at Washington University, New York Genome Center, and the University of Washington
19 Department of Genome Sciences, among others. Other companies and institutions around the world
20 closely follow the research undertaken in the U.S. and the opinions of key opinion leaders in the
21 U.S. in the sequencing field.

22 28. The placement of sequencers with key opinion leaders is also important from a
23 commercial standpoint because key opinion leaders are often large customers that purchase
24 sequencers, consumables, and services for use in their academic work and research, which is a
25 significant market segment and revenue source for Illumina. The U.S. is also an important market
26 for establishing and maintaining relationships with key opinion leaders because the U.S. is the
27 largest sequencing market in the world. Illumina generates over 50% of its revenues from
28 customers in the U.S., and many of Illumina's largest revenue generating customers are key opinion

1 leaders located in the U.S. These key opinion leader-customers include prestigious research
 2 institutions in the U.S. (such as those identified in the preceding paragraph), which buy instruments
 3 and substantial amounts of consumables and services from Illumina.

4 **C. Customers Prefer Not To Frequently Change NGS Instruments.**

5 29. NGS customers tend to show significant loyalty to their initial supplier and are
 6 reluctant to frequently change their NGS instruments or to switch from one supplier to another.
 7 Illumina's next-generation sequencing systems cost between approximately \$20,000 and
 8 \$1,000,000 depending on the type of instrument and model. Purchasing an NGS sequencer is a
 9 significant investment for the customer, particularly academic institutions. The lifespan of most
 10 sequencers is approximately three to five years, and users must be trained before using the
 11 instrument. Once a user becomes trained and familiar with a particular supplier's instruments and
 12 related workflows, they are less likely to switch to another supplier's instruments.

13 30. In addition, the purchase of sequencing instruments also typically involves a service
 14 contract for a period of at least a year, and customers often choose to upgrade their service contracts
 15 so that they run for two to four years. Service contracts typically cover maintenance of the
 16 instrument, including preventative maintenance in which a service engineer will conduct on-site
 17 visits to check the instrument's components to ensure that they are working properly. Service
 18 contracts also typically cover the replacement of Illumina's proprietary core reagents (e.g.,
 19 sequencing-by-synthesis reagents and flow cells) if a fault with the instrument or reagent batch
 20 causes a sequencing run to fail. If that occurs, Illumina sends replacement reagents to enable the
 21 customer to redo the sequencing run at no additional reagent cost. Core reagents are typically
 22 bought in bulk by customers, although they may be purchased in smaller quantities at the
 23 convenience of the customer. For example, customers frequently purchase a 12-18 month supply
 24 of core reagents, which can delivered on a periodic schedule set by the customer.

25 **VI. IF MGI WERE PERMITTED TO INTRODUCE THE MGI SEQUENCERS INTO**
 26 **THE U.S. AS PLANNED, THERE WOULD BE A SUBSTANTIAL RISK ILLUMINA**
 27 **WOULD SUFFER IRREPARABLE HARM**

28 **A. If MGI Follows Through On Its Public Statements Successfully, The MGI**
Sequencers Pose A Competitive Threat To Illumina Products.

31. As a member of the industry and due to my role at Illumina, I am familiar with MGI and the marketing and sales of MGI products. It is well known throughout the industry that the BGI Group and affiliates such as MGI have been seeking to become a provider of SBS products in the U.S. market for years. Ex. BB (“BGI Genomics Raises RMB 547M in IPO,” GenomeWeb (Jul. 14, 2017); *See also* Ex. L (“MGI Prepares To Sell Sequencers In North America, Europe; Announces Proprietary Sequencing Chemistry,” GenomeWeb, (Mar. 4, 2019)(“MGI Article”)). On March 4, 2019, GenomeWeb published an article entitled “MGI Prepares To Sell Sequencers In North America, Europe; Announces Proprietary Sequencing Chemistry” based on interviews with BGI executives. Ex. L (MGI Article). GenomeWeb reported in March 2019 that “the company is currently assembling commercialization teams in North America and Europe and aims to be ready to sell sequencing instrumentation in these markets by the end of this year.” *Id.* at 1. According to GenomeWeb’s interview with Roy Tan, General Manager of MGI Americas, “MGI is also considering a partnership for its US commercialization.” *Id.*

32. It is also known in the industry that MGI is aware of Illumina’s intellectual property rights on SBS technology. In October of 2017, Complete Genomics, Inc. (which is affiliated with MGI) filed two *Inter Partes Review* Petitions to challenge the validity of the ’537 Patent, and the U.S. Patent Office denied both Petitions. In November 2017, GenomeWeb reported that the Mayo Clinic Center for Individualized Medicine based in Rochester, Minnesota was among ten “early-access users” who sent samples to MGI for sequencing analysis, which was performed in China using MGI’s BGISEQ-500 and MGISEQ-2000 (now named the DNBSEQ-G400) sequencers. Ex. M (“BGI’s MGI Tech Launches New Sequencing Platforms, Broadens Scope with Diagnostic Ultrasound System,” GenomeWeb (Nov. 9, 2017)) at 2. The Director of Mayo’s Technology Assessment Group, David Smith, stated that the results “were just as good as Illumina-based sequencing” and said that “he would like to bring the MGISEQ 200 in house but said he believes there are patent issues that prevent MGI Tech from selling the platform in the US at the moment.” *Id.* In a later GenomeWeb article published in 2019, Roy Tan of MGI reportedly “declined to comment on specific intellectual property but said that, in general, MGI scores several factors for making decisions about which territories to enter, and those factors include both regulatory

requirements and IP.” Ex. L (MGI Article) at 2. Illumina has sued MGI for patent infringement in those countries in which Illumina both has patents and has discovered evidence of MGI companies or distributors placing instruments there, including, for example, Switzerland, Germany, Denmark, Sweden, Turkey, the UK, and the U.S.

33. MGI has already been directly competing with Illumina for instrument sales for several years in markets outside of the U.S. MGI has been supplying sequencers using SBS since at least 2016. On January 7, 2019, BGI Group announced that MGI had installed 1,000 MGI sequencers in 16 countries. Ex. N (“MGI Announces Milestone of 1,000 Sequencers Installed and Opens Early Access Program for Groundbreaking Ultra-High-Throughput Sequencer, MGISEQ-T7,” (Jan. 7, 2019), *available at* <https://prn.to/3bTuZrx>). Many people in the industry have recognized MGI’s sequencers as imitative of Illumina sequencing products. For example, based on interviews with MGI, GenomeWeb reported that MGI was using SBS “chemistry [] similar to that used by Illumina and others.” Ex. L (MGI Article) at 4. As mentioned above, MGI itself has touted its own use of the “[p]roven sequencing by synthesis (SBS) chemistry” to potential customers to compete against Illumina. Ex. O (MGI letter to U. Calgary (Nov. 21, 2019)) at 4. When MGI entered the European market, it marketed its sequencers using the designation “MGISEQ,” which is nearly identical to Illumina’s registered European Union trade mark “MISEQ” for its sequencing systems and reagents. An industry commentator observed the remarkable similarity between the appearance and model names of Illumina’s MiSeq and MGI’s copy product, stating that MGI’s product “not only looks like an Illumina (NASDAQ:ILMN) sequencer but they’re actually using the same naming convention as the Illumina machines.” Ex. P (“The BGI Genomics IPO – Is This a Chinese Illumina?,” Nanalyze (Jul. 20, 2017)) at 2. MGI changed the name of its sequencing platforms after Illumina obtained a preliminary injunction in Latvia, the planned location for MGI’s European distribution center, to prevent MGI’s continued trademark infringement.

34. Illumina is a recognized industry leader in DNA sequencing, and our technology is used to generate over 90% of the world’s sequencing data. Ex. Q (Illumina at a Glance) at 1; Ex. D (Next Generation Sequencing (NGS) Market Size, Growth and Trends (2016-2022), DeciBio (Sept. 26, 2019)) at 67 [REDACTED] MGI attempts to

1 position its imitative products as comparable to Illumina's sequencers in performance, while
2 undercutting Illumina on price. Ex. O (MGI letter to U. Calgary (Nov. 21, 2019)) at 3 ("a significant
3 reduction in costs compared to Illumina instruments."); Ex. L (MGI Article) at 3. ("Tan said MGI's
4 platforms will be very cost-competitive with Illumina's."). In a press release of May 21, 2019,
5 MGI claimed that "analyses have shown that MGI's data quality is comparable to data generated
6 using a competitor's [i.e., Illumina's] technology, but that sequencing costs are lower." Ex. R
7 ("MGI introduces total solution for single cell RNA sequencing using flexible, large-scale
8 MGISEQ-2000 sequencing platform compatible with 10x Genomics," MGI (May 21, 2019),
9 *available at* <https://en.mgitech.cn/news/35/>.) MGI further claimed "the data from [MGI's]
10 DNBSEQ™ technology showed comparable excellent performance to that from Illumina
11 technology." *Id.* at 2. [REDACTED]

12 [REDACTED] Ex. D (Next Generation Sequencing (NGS)
13 Market Size, Growth and Trends (2016-2022), DeciBio (Sept. 26, 2019)) at 36, 84.

14 35. The direct competition between Illumina and MGI is also evident in MGI's
15 marketing materials, which often use Illumina's sequencers as a benchmark, typically to make cost
16 comparisons and performance comparisons based on comparative testing. Exhibit S is an extract
17 from a presentation given in Warsaw by an MGI Field Application Scientist that was attended by a
18 customer of one of Illumina's local channel partners. Below is an image from the presentation that
19 illustrates how MGI targets the entire spectrum of Illumina sequencers (from the MiniSeq to the
20 NovaSeq platforms) in its marketing efforts.

Sequencer	DNBSEQ-G50	DNBSEQ-G400	DNBSEQ-T7
Data output/run	15-60 Gb	27.5-1440 Gb	1-6 Tb

Sequencer	MiniSeq	MiSeq	NextSeq	HiSeq 4000	HiSeq X 5/10	NovaSeq 6000
Data Output/run	0.6-7.5 Gb	0.3-15 Gb	30-120 Gb	0.15-1.5 Tb	0.9-1.8 Tb	1-6 Tb

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Ex S. (MGI Poland Presentation) at 120.

36. In this same presentation, MGI provided an “NGS Running Cost Comparison” to support its claim that it provides equivalent NGS performance to Illumina, but at a lower price. *Id.* at 121. MGI’s slides show a list price cost per GB of sequencing from \$10-\$143 for Illumina, as compared to \$5-\$32 for MGI. *Id.* For the highest-production sequencers, MGI shows up to a 75% discount for its DNBSEQ-T7 (\$5 per GB) as compared to Illumina’s NovaSeq (\$10-20 per GB). *Id.* In addition, the typical cost of reagents for sequencing a human genome using Illumina’s NovaSeq 6000 platform is approximately \$800. By comparison, in the above-mentioned GenomeWeb article, MGI advertises its equivalent DNBSEQ-T7 instrument as costing approximately \$500 in consumables per human genome. Ex. L (MGI Article) at 3.

37. Exhibit T is an extract from a presentation given in Canada by Stephen Rogers and Ben Li, which shows additional MGI marketing efforts to directly compete against Illumina. Ex. T (MGI Canada Presentation) at 24 (comparing MGI’s DNBSEQ-G50 with Illumina’s MiSeq and NextSeq 500/550), 32 (comparing MGI’s DNBSEQ-G400 with Illumina’s NextSeq 550), 33 (comparing MGI’s DNBSEQ-G400 with Illumina’s NovaSeq), 36 (comparing MGI’s DNBSEQ-G400 and MGISEQ-T7 with Illumina’s NovaSeq and HiSeq), 42, 47. For example, MGI touts “a highly comparable performance between [Illumina’s] NovaSeq 6000 and [MGI’s] MGISEQ-2000 [now named the DNBSEQ-G400] in sequencing quality, and cell, UMI, and gene detection.” *Id.*

1 at 42, 47.

2 38. In “The Sequencing Buyer’s Guide” (which is sponsored by MGI, among others),
 3 David Smith of the Mayo Clinic identifies “BGI-based sequencing” as a lower-cost substitute for
 4 Illumina’s technology. He states, “[o]ne of the most attractive aspects of BGI-based sequencing is
 5 that they offer a price-point for WGS [whole genome sequencing] that is really hard to beat of \$600.
 6 This is an all-in cost of library preparation, sequencing and post-sequencing analysis. As will be
 7 discussed later in this report, this is considerably less than the full cost of WGS on the only other
 8 viable platform for WGS, namely Illumina.” Ex. JJ (“The Sequencing Buyers Guide,” Front Line
 9 Genomics (2019) at 14). Mr. Smith also notes in The Sequencing Buyer’s Guide that BGI’s
 10 sequencers (such as the BGISEQ-500) “were mainly sold in China (most likely due to patent issues
 11 on the actual sequencing chemistry)” and further mentions that “there were a number of patent
 12 violation lawsuits filed between Illumina and MGI.” *Id.* at 13-14

13 39. MGI targets Illumina’s existing customers and attempts to use existing Illumina
 14 infrastructure to induce Illumina’s customers to replace their Illumina sequencers with MGI
 15 products, touting MGI’s “[c]ompatibilty with previous Illumina platforms.” Ex. O (MGI letter to
 16 U. Calgary) at 4. For example, MGI markets its DNBSEQ instruments as being “fully compatible
 17 with lab infrastructure that has been set up previously with Illumina’s instrumentation,” stating that
 18 they generate files that are “compatible with bioinformatics workflows written for sequencing data
 19 from Illumina instruments” and that “[l]ibraries already constructed with Illumina-style adapters
 20 can be converted easily to [MGI’s] platform.” *Id.* at 4-5.

21 40. The sequencing-by-synthesis method used by MGI works the same way as Illumina’s
 22 machines, by incorporating 3’-blocked nucleotides into a nucleic acid on a “flow cell” (which looks
 23 similar to a microscope slide) and imaging the results. The above-mentioned article by
 24 GenomeWeb explains that MGI’s “current sequencing chemistry relies on stepwise sequencing-by-
 25 synthesis (SBS) where 3’-blocked nucleotides are labeled with cleavable fluorescent dyes, which
 26 leave a molecular ‘scar’ after they are removed. This chemistry is similar to that used by Illumina
 27 and others.” Ex. L (MGI Article) at 4. MGI takes advantage of the fact that its products use the
 28 same SBS method that Illumina has established as the most reliable, accurate and cost-efficient

1 sequencing method. As mentioned above, MGI itself claims to use “[p]roven sequencing by
 2 synthesis (SBS) chemistry” to compete against Illumina. Ex. O (MGI letter to U. Calgary) at 4.
 3 MGI has been directly competing against Illumina in foreign markets by selling sequencing
 4 instruments and related consumables since MGI was founded in 2016.

5 41. On May 11, 2019, MGI announced via press release that it had raised over \$200
 6 million, which it claims “will help China in the life sciences and industrial high-end equipment
 7 manufacturing to achieve a leap from tracking to leading.” Ex. U (MGI Announces US\$200 Million
 8 in First Round Fundraising, MGI Press Release (May 11, 2019), *available at* [https://en.mgitech.cn](https://en.mgitech.cn/News/info/id/38)
 9 [/News/info/id/38](https://en.mgitech.cn/News/info/id/38)) at 6. MGI claims that it is now “catching up with the industry giants in terms of
 10 originality of technical products.” *Id.*

11 42. MGI also uses marketing similar to that of Illumina’s to emphasize that it provides a
 12 complete and integrated solution as a “one-stop shop” for all of the customer’s sequencing needs.
 13 For example, Illumina’s Sequencing Systems brochure emphasizes the integrated nature of our
 14 sequencing technology and advertises all our sequencers as offering “[o]ne seamless process. One
 15 *complete resource.*” (Ex. E (Sequencing Systems brochure) at 15 (emphasis added)). In the
 16 brochure for its competing DNBSEQ-G50 sequencer, MGI similarly emphasizes that it is a
 17 “Complete Solution” for both research and “Clinical Applications,” providing an “end-to-end
 18 solution from sample to sequencing report.” Ex. V ((DNBSEQ-G50 Brochure) at 4, *available at*
 19 <https://bit.ly/2V7SAyS>). MGI similarly markets its competing DNBSEQ-G400 sequencers as a
 20 “Total Solution” from sample preparation to final report that provides a “simplified and streamlined
 21 sequencing experience.” Ex. W ((DNBSEQ-G400 Brochure) at 2, *available at*
 22 <https://bit.ly/37KmGeq>).

23 43. MGI also offers data analysis software to accompany the actual sequencing
 24 instrument that is similar to Illumina’s offering. Illumina offers a variety of bioinformatics software
 25 to run with its sequencers. For example, the MiSeq runs through BaseSpace Sequence Hub,
 26 Illumina’s cloud-based interface, the analytical software tool MiSeq Reporter Software. Ex. X
 27 (Illumina MiSeq System – Focused power for targeted gene and small genome sequencing,
 28 *available at* <http://www.illumina.com/systems/miseq/system.html>). As another example, the

MiniSeq runs a software program called Local Run Manager. Ex. Y (MiniSeq brochure) at 5. MGI's brochure for a competing product similarly states that it provides an "integrated data analysis platform" to "download, store and manage sequencing data and offer an end-to-end solution from sample to sequencing report." Ex. V (DNBSEQ-G50 brochure) at 4. As mentioned above, MGI has also marketed its products as being fully compatible with Illumina's platforms and related lab infrastructure, including Illumina's libraries and bioinformatics workflows. Ex. O (MGI letter to U. Calgary) at 4-5.

44. MGI has also marketed a "follower" product to compete with Illumina's DRAGEN Bio-IT Platform. DRAGEN (Dynamic Read Analysis for GENomics) uses reconfigurable FPGA (field-programmable gate array) technology to provide hardware-acceleration of genomic analysis algorithms to enable labs to more quickly, flexibly, and cost-efficiently analyze their genomic data. Ex. Z (Illumina DRAGEN Bio-IT Platform: Enabling the global genomic infrastructure), *available at* <https://bit.ly/2woHtaq>. MGI responded to DRAGEN by offering its "MegaBOLT bioinformatics analysis accelerator," which also uses an FPGA circuit to provide "a more flexible and efficient solution for gene data analysis." Ex. AA (MegaBOLT: Bioinformatics analysis accelerator-MGI, *available at* <https://bit.ly/2P9LeHl>).

B. If MGI Were Permitted To Distribute Its SBS Products In The U.S., There Is A Substantial Risk That Illumina Will Incur Reputational Harm, Lost Business Opportunities, and Price Erosion.

1. MGI's Plans to Distribute Its Platforms in the U.S.

45. In 2017, the President of BGI Genomics (a subsidiary of the BGI Group), Wang Jian, stated publicly that the company plans to "dominate the market" in the field of genomics, as part of raising money for its IPO. Ex. BB ("BGI Genomics Raises RMB 547M in IPO", GenomeWeb (Jul. 14, 2017) *available at* <https://bit.ly/2P7TZSl>). Since then, MGI claims that it has been gaining traction in markets abroad. By January 7, 2019, BGI had announced that MGI had installed 1,000 MGI sequencers in 16 countries. Ex. CC ("MGI Announces Milestone of 1,000 Sequencers Installed and Opens Early Access Program", PR News Wire Article (Jan. 7, 2019), *available at* <https://prn.to/38IO4uK>). On January 9, 2019, MGI claimed that it had achieved a 35% market share in China and that "[t]he MGI platform is gaining support around the world." Ex. DD ("MGI

1 Announces Price and Early Access Customer of MGISEQ-T7”, PR News Wire Article (Jan. 9,
2 2019), *available at* <https://prn.to/2uNQqdb>). On January 14, 2020, MGI announced a partnership
3 with Swift Biosciences, Inc., referencing “MGI’s fast growing install base.” Ex. EE (Swift
4 Biosciences Partners with MGI for High Throughput Genomic Sequencing, MGI Press Release
5 (Jan. 14, 2020), *available at* <https://en.mgitech.cn/news/127/>).

6 46. I understand that MGI’s counsel has recently provided notice that MGI intends to
7 distribute sequencers and reagent kits using the NGS chemistry accused of infringement to key
8 opinion leaders in the U.S. on a “no-cost trial basis.” Ex. FF (MGI email chain of January 24-
9 February 13, 2020) at 14. I further understand that MGI’s counsel denies that this would be a
10 “commercial use” and further stated that it would be “for purposes of soliciting feedback on the
11 sequencers and comparative testing with Defendants’ recently developed sequencing chemistry,
12 which is not the subject of this litigation.” *Id.* at 11. MGI’s counsel also stated that MGI is planning
13 to provide its DNBSEQ-G400RS sequencing system to “five or fewer KOLs [key opinion leaders]
14 on a no-cost basis,” but declined to identify any of these key opinion leaders. *Id.* at 7. I have been
15 informed that the DNBSEQ-G400RS system is included in the accused products in the pending
16 U.S. litigation. MGI’s counsel further indicated that MGI plans to provide both the “accused
17 reagent kits” and reagents to the key opinion leaders, including “Defendants’ recently developed
18 sequencing chemistry,” and that both types of reagents work with the DNBSEQ-G400RS sequencer
19 that MGI plans to distribute. *Id.* at 11. MGI’s counsel also provided the following non-exhaustive
20 list of reasons for its planned distribution of sequencers and reagents into the U.S.: “(i) the kits can
21 be used for important scientific research and KOLs desire choices in sequencing technology; (ii) in
22 certain instances, MGI has ongoing R&D projects with KOLs where the sequencing is currently
23 performed by MGI or its affiliates, but KOLs may prefer to do their own sequencing experiments;
24 and (iii) KOLs may want to compare the accused and unaccused reagent kits.” *Id.* at 8.

25 2. Reputational Harm to Illumina

26 47. I disagree with MGI’s claims that its planned distribution of sequencers and reagents
27 to “five or fewer KOLs on a no-cost basis” in the U.S. would not be a commercial activity and
28 would only be an “incidental” use. As explained above, in the genetic sequencing field, targeted

1 engagement with a limited number of key opinion leaders is a typical part of a commercial launch
2 strategy. Key opinion leaders tend to be customers that often purchase instruments and substantial
3 amounts of consumables and services for use in their academic work and research, which is a
4 significant market segment and revenue source for Illumina. MGI has marketed its DNBSEQ-G400
5 in this segment in direct competition with Illumina's sequencers, including for example, the
6 NextSeq, HiSeq, and Novaseq. Ex. T at 32-33, 36, 42, 47. Illumina and others in the industry often
7 engage with a select number of key opinion leaders as a normal part of their commercial rollouts
8 and product marketing efforts. Allowing MGI to place its NGS sequencers with even a limited
9 number of key opinion leaders in the U.S. would have commercial consequences that would likely
10 cause irreparable harm to Illumina's business and brand.

11 48. As explained above, the placement of sequencers with key opinion leaders is
12 important for a supplier's commercial reputation because key opinion leaders (which are often
13 associated with prestigious universities or research centers) can have substantial influence on the
14 industry's perception of a brand and the purchasing decisions of other customers in the field. The
15 U.S. market is especially critical for establishing and maintaining relationships with key opinion
16 leaders because the U.S. includes a high concentration of key opinion leaders, including world
17 renowned institutions with global reputations in sequencing expertise. Other companies and
18 institutions around the world pay close attention to research undertaken in the U.S. and the opinions
19 of key opinion leaders in the U.S. Placing sequencers with key opinion leaders in the U.S. provides
20 an opportunity for a supplier to receive enhanced exposure globally. The U.S. has been a critical
21 market for building the reputation of Illumina's technology in both the U.S. and beyond by
22 establishing that it is trusted by world-leading institutions in the U.S., including the key opinion
23 leaders that I identified above. Illumina has leveraged its success in the U.S., including the publicity
24 and goodwill due to U.S. key opinion leaders adopting Illumina's technology, in marketing and
25 sales efforts when approaching new customers both in the U.S. and other countries.

26 49. MGI's proposal to place its instruments with "five or fewer KOLs on a no-cost basis"
27 is similar to the commercial strategies that it has used in other countries such as the UK and
28 Germany to seed the market as part of its attempted commercial rollout in those countries to

1 compete against Illumina. Part of this strategy is to get instruments placed with key opinion leaders
2 to get them comfortable with and accustomed to MGI's platforms, while giving MGI credibility in
3 the marketplace. This is not an "incidental" use. Placing instruments in the U.S. lays the necessary
4 groundwork for commercialization. The publicized use of MGI's products by even a small number
5 of key opinion leaders would also generate buzz in the market so that word about the technology
6 would spread among peers in the industry to drive sales. Many key opinion leaders are large
7 institutions that use large quantities of consumables, so MGI's plan would also give it the
8 opportunity to ultimately make substantial revenues on consumables used with MGI's instruments,
9 even if the instruments were initially placed on a no-cost trial basis. This plan would give MGI a
10 key entry point into the U.S. market and allow MGI to embed itself with Illumina's current and
11 potential key opinion leader-customers in the U.S., while taking their time and mindshare away
12 from Illumina's products, as MGI performs installs, troubleshooting, training, and services for these
13 customers once MGI's instruments are placed.

14 50. The placement of sequencers by MGI with "five or fewer KOLs on a no-cost basis"
15 in the U.S. would likely cause serious harm to Illumina's commercial reputation in the field, as well
16 as its relationships with key opinion leaders, while unjustly enhancing MGI's reputation and
17 relationships with these key opinion leaders and other U.S. customers. This would encourage others
18 in the field to use MGI's sequencers, reagents, and services instead of Illumina's competing
19 products and services. If key opinion leaders publicly switch from Illumina's products to MGI's
20 products, then it would cause substantial harm to Illumina's reputation and brand. It would not be
21 possible to quantify the harm that would be caused to Illumina's commercial reputation and key
22 opinion leader relationships if MGI were allowed to develop relationships with these key opinion
23 leaders and inroads into the U.S. market by piggybacking off of Illumina's technology in the '537
24 and '200 Patents. Likewise, it is not possible to put a dollar figure on the lost opportunities that
25 would result or the broader impact to Illumina that would occur if MGI were allowed to using
26 infringing technology to develop relationships with key opinion leaders to promote MGI's products
27 and likely cause other companies and institutions around the world to choose MGI's products over
28 Illumina's products.

51. Assuming that MGI follows through on its stated intention to distribute its products to “five or fewer KOLs on a no-cost basis,” this would not mitigate the harm to Illumina. Because key opinion leaders tend to be prestigious institutions that are highly visible in the marketplace, providing infringing MGI products to even a small number of key opinion leaders (e.g., less than five) would likely cause substantial harm to Illumina’s reputation, brand, and market position. A small number of key opinion leaders can influence many other key players in the marketplace, and the potential harm is even more severe in a relatively nascent, growing market such as NGS. Further, key opinion leaders are often large Illumina customers or potential customers that purchase sequencers and relatively large quantities of consumables and services. So distribution of infringing MGI products to even a small number of key opinion leaders creates a serious risk of substantial lost sales and business opportunities. Similarly, even if MGI’s penetration into the U.S. market is limited to “five or fewer KOLs on a no-cost basis,” MGI’s presence would create a serious risk of price erosion for Illumina. As discussed further below, current and prospective Illumina customers often use MGI’s presence and cut-rate pricing to negotiate and attempt to extract price concessions from Illumina. If MGI is offering sequencers to key opinion leaders “on a no-cost trial basis,” these and other customers would likely pressure Illumina for discounts. And once one customer receives a discount, then other customers will expect the same.

52. That MGI would provide its instruments on a “no-cost trial basis” or use them for comparative testing and to solicit feedback does not negate the harm to Illumina, it underlines it. As shown in the GenomeWeb article above, MGI announced early last year that it plans to penetrate the U.S. sequencing market, and MGI’s planned placement of sequencers with key opinion leaders is a first step toward gaining a foothold in the U.S. market so that it can eventually erode Illumina’s market share. Allowing key opinion leaders to try MGI’s accused sequencing systems on a “no-cost trial basis” would have the effect of trying to encourage these opinion leaders – and others – to purchase the accused technology instead of purchasing Illumina’s technology. The goal of such placements is precisely to entice such opinion leaders and others to prefer MGI’s technology – or at least prefer its lower price – rather than Illumina’s products. MGI’s pitch in its global competition with Illumina outside the United States is providing the same technology at lower cost. If MGI is

1 allowed to distribute its products in the U.S., that would likely result in key opinion leaders and
2 those they influence delaying purchases of Illumina instruments and consumables or demanding
3 discounts. This is irreparable harm that is difficult to identify and fairly quantify on a customer by
4 customer basis. Even if MGI is simply trying to get a head start on its marketing efforts before the
5 patents expire in a few years, that is irreparable harm because it would damage Illumina's reputation
6 and brand, and as discussed further below, it would cause Illumina to lose business opportunities,
7 harm Illumina's customer relationships and goodwill, and force discounting that would cause
8 irreversible price erosion.

9 53. Alternatively, if MGI is using the accused technology to encourage certain key
10 opinion leaders and those they influence to get accustomed to MGI products, including its
11 sequencers, so it can later sell a different sequencing chemistry, that is an improper commercial use
12 of the accused technology that will cause the same reputational harm to Illumina explained above,
13 while also inflicting lost market share and eroded pricing for the reasons discussed below. MGI
14 should not be allowed to infringe Illumina's patents for comparative testing to disparage Illumina's
15 technology, promote a different sequencing chemistry, or as any other part of its commercial launch
16 strategy. Nor should MGI be allowed to leverage its use of Illumina's already-proven, patented
17 NGS technology to seed the U.S. market by placing instruments and developing KOL-customer
18 relationships, which is a commercial activity because it removes barriers to commercial entry and
19 paves the way for MGI to sell current and new reagents, other consumables, and services going
20 forward.

21 54. MGI's product give-away plan is not credibly for conducting research to develop
22 new sequencers or reagents. As mentioned above, it is the same commercial strategy that MGI used
23 in other countries such as the UK and Germany to seed the market as part of its attempted
24 commercial rollout in those countries. I am not aware of any reason why MGI cannot perform
25 research to develop new products in, for example, China, where MGI claims to already have a 35%
26 market share, or in a jurisdiction where Illumina does not have patents covering the technology.
27 MGI does not need to do R&D on the current, accused NGS chemistry in the U.S. in part because
28 it is based on Illumina's already-proven Solexa sequencing, which MGI has been offering in other

1 markets since at least 2016. As mentioned above, MGI has reportedly supplied over 1,000
 2 sequencers to hundreds of users outside the United States as of 2019. And the only sequencer
 3 identified by MGI that it plans to distribute in the U.S. is the DNBSEQ-G400. MGI does not
 4 credibly need to distribute this sequencer to U.S. key opinion leaders to receive feedback on it or
 5 conduct research into its development because MGI launched the DNBSEQ-G400 (then called the
 6 MGISEQ-2000) back in October 2017 and has been selling it ever since. Ex. GG (“MGI Tech
 7 MGISEQ-2000, MGISEQ-200 Sequencers; MGIFLP Modular NGS Workstation; MGIUS-R3
 8 Robotic Ultrasound System”, GenomeWeb (Oct. 31, 2017), *available at* <https://bit.ly/2SXSzJj>).
 9 MGI also does not credibly need to distribute its instruments to key opinion leaders in the U.S. in
 10 order to perform research and development on its “new chemistry” because MGI has already done
 11 this elsewhere and published the results. Ex. HH (“MGI Demonstrates Success of New CoolMPSTTM
 12 Sequencing Chemistry on PCR-free DNBSEQTM Platform,” BioSpace (Oct. 17, 2019), *available*
 13 *at* <https://bit.ly/32a5bD7>).

14 55. Further, MGI/BGI has no need to place instruments in the U.S. in order to conduct
 15 research and development, do comparative testing, or solicit feedback because this can be done
 16 through BGI’s existing “test send out” service through which it contracts with companies and
 17 institutions to analyze samples remotely in its laboratories in China. MGI’s counsel stated that
 18 “MGI has ongoing R&D projects with KOLs where the sequencing is currently performed by MGI
 19 or its affiliates, but KOLs may prefer to do their own sequencing experiments.” Ex. FF (MGI email
 20 chain of January 24-February 13, 2020) at 8. This shows that MGI is capable of using its “test send
 21 out” services to perform sequencing services for “ongoing R&D projects with KOLs” in its
 22 laboratories in China, and there is no credible need to distribute the accused sequencers to key
 23 opinion leaders in the U.S. other than for marketing and commercialization.

24 56. MGI/BGI also has the option of inviting key opinion leaders to its facilities and
 25 laboratories in China to use MGI’s instruments there. This is standard practice in the industry.
 26 Illumina frequently invites key opinion leaders and potential customers from other countries to visit
 27 its facilities in San Diego to learn about Illumina’s technology. Put simply, MGI has not identified
 28 any reason why it cannot conduct comparative testing or solicit feedback from users in another

country without infringing Illumina's patents. And MGI has not provided any reason why it needs to place its products with prominent "key opinion leaders" (who are visibly positioned to be able to promote MGI's products in the marketplace) in the U.S. other than for marketing and commercialization purposes.

3. Lost Business Opportunities and Customer Relationships

57. As explained above, the NGS market is rapidly growing both globally and in North America, and MGI is a direct competitor to Illumina. Illumina has already lost sales and business opportunities to BGI and MGI in foreign markets and has received requests for lower pricing from potential customers in response to marketing by MGI and BGI. For example, on December 10, 2019, Illumina lost a potential contract to deliver sequencing services for a large-scale project with the Department of Health in Abu Dhabi because it was awarded to MGI/BGI. I understand that we received feedback that Illumina did not win the contract because MGI/BGI had offered a lower price. Illumina has also recently lost prospective contracts in Canada due to price undercutting by MGI/BGI. For example, Illumina recently lost a tender to MGI for the purchase of a sequencer by the University of Toronto.

58. As mentioned above, MGI specifically targets Illumina's existing and potential customers and even advertises NGS products as compatible with Illumina's platforms and infrastructure to promote the replacement of existing Illumina sequencers in the marketplace. MGI also routinely pursues Illumina's existing customers by offering to buy back their Illumina instruments if they agree to replace them with MGI's products. There is substantial risk that MGI's distribution of NGS products into the U.S., if permitted, would cause Illumina loss of potential market share and lost opportunities to enhance its brand reputation in the industry.

59. As discussed above, many of Illumina's largest customers on a revenue basis are key opinion leaders in the U.S., and Illumina generates significant revenues from university researchers that use our instruments, reagents, and/or associated services in their research. The statement by MGI's counsel that "(i) the [MGI] kits can be used for important scientific research and KOLs desire choices in sequencing technology" shows that MGI's planned product distribution would directly compete against Illumina for sales of products, consumables, and services in the market for

1 scientific research, a large commercial market segment. The same is true for the “ongoing R&D
2 projects with KOLs” mentioned by MGI’s counsel. Ex. FF (MGI email chain of January 24-
3 February 13, 2020) at 8. On the other hand, if by “ongoing R&D projects with KOLs,” MGI is
4 instead referring to R&D projects limited to developing MGI’s sequencers or its “new chemistry,”
5 then MGI has no true need to place accused sequencers with key opinion leaders in the U.S. to do
6 either of these things for the reasons explained above.

7 60. Consequently, the placement of sequencers by MGI with “five or fewer KOLs on a
8 no-cost basis” in the U.S. would likely cause serious harm to Illumina’s relationships with key
9 opinion leaders and its revenue stream from lost sales of instruments, reagents, and services to key
10 opinion leaders who receive substitute products from MGI on a “no-cost trial basis.” MGI can offer
11 free giveaways (and ultimately artificially low prices) at least in part because it has not had to incur
12 the substantial research and development costs expended by Illumina to develop the Solexa
13 sequencing and other innovations that are the subject of Illumina’s patents. If a potential customer
14 spends the time to become trained in the use of an MGI sequencing instrument, becomes familiar
15 with it, and finds that it provides comparable performance to Illumina’s industry leading NGS
16 technology, the customer will be more likely to purchase it or other products from MGI in the
17 future. Price is an important differentiator because MGI’s products offer the technical benefits
18 associated with Illumina’s Solexa sequencing (e.g., high accuracy and high throughput) due to
19 MGI’s use of Illumina’s patented technology. Thus, MGI’s ability to undercut Illumina on price
20 through infringement makes the risk of lost sales highly likely. Unless Illumina were to make
21 significant price reductions in response to MGI’s artificially low prices, Illumina would not only
22 lose revenue from the supply of the sequencing platforms, it would also lose the associated ongoing
23 revenue streams from the supply of its reagents and sequencing services to key opinion leaders and
24 others.

25 61. Additionally, BGI offers remote genomics sequencing services and enters into
26 contracts with companies and institutions to analyze samples remotely in its laboratories in China.
27 If MGI is allowed to place sequencers in the U.S. with “five or fewer KOLs on a no-cost basis,”
28 then those institutions that trial MGI’s sequencing technology will not necessarily return to using

1 Illumina's platform when the trial ends. If they spend the time to become trained and familiar with
 2 using MGI's infringing products, while becoming accustomed to MGI's artificially low prices for
 3 consumables, there is a substantial risk that they could ultimately purchase MGI's instruments and
 4 consumables, or opt to send samples for remote analysis to BGI in China, knowing that they will
 5 use the same MGI platforms there. Because many sequencing projects are long term, a company
 6 or institution using the MGI platform for sample analysis may decide to continue having MGI/BGI
 7 analyze further samples, rather than change their protocol mid-project and move back to an Illumina
 8 platform. This would be an on-going risk to Illumina, and the resulting harm would not be easily
 9 quantifiable.

10 **4. Forced Discounting and Price Erosion**

11 62. If MGI follows through on its plan to distribute NGS products to "five or fewer KOLs
 12 on a no-cost basis" in the U.S., there is also a substantial risk that Illumina will feel pressure to
 13 irreversibly discount prices on Illumina sequencers. MGI can do this on a "no-cost trial basis" to
 14 seed the market while developing customer relationships, goodwill, and brand recognition.
 15 Because NGS customers tend to show significant loyalty to their initial supplier and are reluctant
 16 to change sequencing instruments once they become accustomed to them, it would be more difficult
 17 for Illumina to get traction with potential customers once MGI has already distributed NGS
 18 products to them, even if on a no-cost trial basis. This harm would be irreversible and irreparable,
 19 at least because the impact on Illumina's customer relationships, customer goodwill, brand, and
 20 change in pricing structure cannot be easily quantified.

21 63. Illumina has already experienced price erosion outside the U.S. caused by MGI/BGI.
 22 For example, Illumina has already been forced to lower its prices in China due to competition from
 23 MGI/BGI. Illumina has seen price erosion in the research market in China as a result of MGI/BGI
 24 pricing at between approximately 20-50% below current market prices. As such, Illumina expects
 25 that it may be forced to offer further discounts in the near future in China.

26 64. Illumina is also under increasing pressure to reduce its pricing in Germany due to
 27 MGI/BGI. We have learned from our current and potential customers that MGI/BGI has been
 28 targeting customers currently using NGS systems (very often Illumina systems), as well as potential

1 customers who are not yet using NGS. For example, a director at a very large oncology institute in
2 Germany (a key opinion leader which is a significant customer of Illumina) has reported receiving
3 phone calls from BGI on a weekly basis for some time regarding its sequencing technology. We
4 believe that MGI/BGI has been placing some sequencers in Germany free of charge, while only
5 charging for reagents and services at artificially low prices. As a result, MGI/BGI is now competing
6 against Illumina for product placements and sales at institutions all over Germany. The extent of
7 price reductions that Illumina will need to make to remain competitive is unpredictable.

8 65. If MGI were allowed to distribute its NGS products to “five or fewer KOLs on a no-
9 cost basis” in the U.S., Illumina would likely have to offer substantial discounts or be faced with a
10 loss of business and damage to its longstanding customer relationships. If Illumina were to reduce
11 its prices to the levels that would likely be required to compete against MGI’s free giveaways (or
12 its artificially low prices in markets abroad), Illumina’s pricing on its sequencing systems will be
13 permanently eroded. Even if MGI had to later withdraw from the U.S. market after litigation
14 concludes, Illumina would not be able to raise its prices back up to sustainable levels without
15 significantly harming its customer relationships and goodwill. As such, any discounting that
16 Illumina is forced to undertake in response to MGI’s distribution of products into the U.S. would
17 likely be irreversible.

18 66. If Illumina is forced to provide discounts to one customer in response to competition
19 from MGI, then it will likely be forced to provide discounts to other customers. Companies and
20 institutions often collaborate on sequencing projects (which can include sharing the costs of
21 purchasing equipment and/or consumables), which means that information about pricing is often
22 shared between companies and institutions. Key opinion leaders in particular frequently collaborate
23 and are even more likely to share pricing information. Illumina also participates in numerous
24 tenders in which pricing information is disclosed. Any discounting by Illumina will impact the
25 expectations of its current and future customers, which will have an unpredictable effect on pricing
26 across the market. In markets abroad, current and prospective Illumina customers often use MGI’s
27 presence in the market and cut-rate pricing to negotiate and attempt to extract price concessions
28 from Illumina, even if the customers ultimately do not purchase or use MGI’s products. The amount

1 of this damage to Illumina cannot be easily quantified.

2 67. Consequently, if MGI is permitted to distribute products to “five or fewer KOLs on
3 a no-cost basis” in the U.S., there would be significant unquantifiable losses caused by the damage
4 that would be done to Illumina’s commercial reputation and inability to charge prices in the future
5 that reflect the value of its innovations. MGI’s plan to provide free giveaways does not include
6 comparable research and development costs to what Illumina expended for its patented
7 contributions.

8 68. The types of injuries I discuss are irreparable because the impact on Illumina’s
9 business would be complex, and it would be difficult to comprehensively quantify losses in
10 reputation, market share, lost business opportunities, cost of sales, or the impact of pricing
11 pressures. For example, losing business opportunities is different from losing sales in an ordinary
12 market environment. In an ordinary market, records of past revenues help quantify the injury. But,
13 with regard to lost business opportunities that Illumina could have had but did not as a result of
14 infringement, there are likely to be no financial records that would help quantify the harm since
15 these would be new customer relationships in a nascent market. Likewise, it would be difficult to
16 trace and quantify by reviewing financial records the effects of damage to our market reputation.
17 It is especially difficult to capture the full scope of these types of losses when the market is at this
18 sensitive time of growth. This is why there is a substantial risk that these harms would be
19 unquantifiable and irreparable.

20 69. In addition, it is unclear whether MGI would be able to satisfy a money judgment for
21 infringement at the conclusion of the pending litigation in the U.S. I am unaware of any evidence
22 or indication that MGI has been profitable in any fiscal year since it was founded in 2016. In 2019,
23 it was reported that the BGI Group (of which MGI is an affiliate) only secured one-fifth of the
24 expected amount of funding from investors. Ex. II (“Genome Sequencing Giant BGI’s Fundraising
25 Flops”, Caixinglobal.com (May 10, 2019) at 1, *available at* <https://bit.ly/2udsrUp>). It is also unclear
26 what assets MGI maintains in the U.S.

27 70. I declare under penalty of perjury of the laws of the United States of America that
28 the foregoing is true and correct to the best of my information and belief.

1 Dated: February 19, 2020
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A handwritten signature in blue ink, appearing to read "Mark Van Oene", is positioned above a horizontal line.

MARK VAN OENE